U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-05

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-005

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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and contractors from the Center for Nuclear Waste Regulatory Analyses observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division audit of the Waste Package Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-005, was conducted on January 31 through February 4, 2000, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected analysis model reports (AMRs) supporting the Waste Form PMR. During the audit, selected AMRs were subjected to a technical review as well as a review to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA are properly implementing the provisions contained in the QARD and the requirements contained in Subpart G, "Quality Assurance," to Part 60, of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting the SR are properly qualified; and 2) reviewing the progress being made by the DOE and its contractors in meeting the qualification goals for the SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM Quality Assurance (QA) Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for selected AMRs supporting the Waste Form PMR. During the conduct of the audit, both the audit team and the NRC observers reviewed the AMRs, within the scope of the audit, and their supporting data and software. Because the AMRs reviewed were in draft and in the process of being completed, the DOE audit served more as a review than as an assessment with. There were no deficiencies being written. The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. During the audit, several recommendations were made to improve the AMR preparation process.

The NRC staff generally agrees that OQA Audit M&O-ARP-00-005 was effective in recommending improvements in the AMR process and with the audit team conclusions, findings, and recommendations. The audit was conducted in a professional manner, using audit team members who were independent of the activities they audited. The DOE audit team members appeared to be knowledgeable in the QA and technical disciplines within the scope of

the audit, and their qualifications were found to be acceptable for their respective disciplines. Although the audit scope included data qualification, the audit team was unable to assess the data qualification process and activities because no data qualification activities had been performed for the data supporting the AMRs reviewed. The NRC staff considers the lack of data qualification activities during this audit and the four previous PMR audits to be a condition requiring OQA management attention.

During the observation, the DOE provided information on the progress in reaching its goal of having 50 percent of the data supporting the Site Recommendation Considerations Report (SRCR) completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or data tracking numbers (DTNs) out of a projected 1600 DTNs. The DOE explained that the total number of DTNs was still evolving because several AMR preparers had not entered data supporting the AMRs into the DTN tracking system.

The NRC observers concluded that: (a) the AMR developers, within the scope of this audit, produced technically adequate AMRs; however, both the NRC observers and OQA audit team members provided several comments on the technical content of the AMRs; (b) the Document Input Reference System, which is used to track DTNs, has improved; and (c) the implementation of changes to procedures controlling the AMR process and the communicating of lessons learned from the audits to the preparers of the AMRs could be improved by providing additional training or formal instruction.

NOTE: **[Subsequent to the inspection, OQA decided to postpone the remaining 3 PMR audits that were scheduled to be performed during the months of March and April 2000. This decision was made, in part, because several AMR completion dates had slipped and lessons learned from the previous 6 PMR audits needed to be communicated to the preparers of the AMRs.]**

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Larry Campbell	Team Leader	NRC
Tae Ahn	Technical Specialist	NRC
Tom Trbovich	Senior QA Engineer	CNWRA
David Pickett	Technical Specialist	CNWRA

3.2 OQA Audit Team

Kristi Hodges	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Patrick Auer	Auditor	OQA/QATSS
Victor Barish	Auditor	OQA/QATSS
James Baylock	Auditor	OQA/QATSS
Frank Wong	Technical Specialist	Management and Technical Services(MTS)
Robert Fish	Technical Specialist	MTS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited-scope, performance-based audit of activities and processes related to the development of the AMRs supporting the Waste Form PMR. AMRs, software, and abstractions were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. Several procedures, including the ones listed below, were used by the audit team and the NRC observers during the audit:

a) AP-2.13Q, "Technical Product Development Planning," Revision 0, with Interim Change Notice (ICN) No. 1.

b) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 2.

c) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1.

d) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 2.

e) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 1.

f) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0.

g) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0, with ICN No. 2.

h) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1.

i) QAP-SIII-1, "Scientific Investigations," Revision 3.

The Waste Form PMR addresses the behavior of various waste forms, such as commercial spent nuclear fuel and high-level waste glass, and includes topics such as cladding protection, waste form degradation, and radionuclide release. The OQA selected the following four Waste Form AMRs for review during the audit:

a) AMR No. F0115 (ANL-WIS-MD-000012), "Waste-Form Colloid-Associated Concentration Limits," (Draft) Revision 00A.

b) AMR No. F0105 (ANL-EBS-MD-000021), "Colloid Stability and Attachment/Detachment Properties," (Draft) Revision 00A.

c) AMR No. F0110 (ANL-EBS-MD-000020), "Colloid-Associated Radionuclide Concentration Limits," (Draft) Revision 00A.

d) AMR No. F0045 (ANL-EBS-MD-000048), "Initial Cladding Condition," (Draft) Revision 00A.

All AMRs reviewed were drafts and at Revision 00A and were in the process of being revised in response to their initial checking. After the incorporation of the checker's comments, the AMRs will be subjected to an additional technical review.

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate in-process Waste Form PMR activities. However, the audit team was unable to confirm that data supporting the AMRs had been properly qualified because no qualification activities had been initiated by M&O for these data. The NRC staff suggests that OQA management evaluate the need to conduct audits and surveillances specifically to evaluate the qualification of data.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management were held each morning to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

The qualifications of the audit team leader and the OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they reviewed during the audit. One technical specialist had previously worked in M&O, but did not have responsibility for any AMR reviewed during the audit. In addition, training, education and experience records for audit team members were reviewed and found acceptable. Further, the NRC observers reviewed the technical specialists' qualifications (resumes) and found that the technical specialists had sufficient technical education, training, and experience related to the AMRs reviewed.

4.4 Examination of Q A Elements

The OQA programmatic and technical audit activities were conducted simultaneously, using sub-audit teams consisting of a technical specialist and a QA auditor. The limited-scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of applicable QA elements. The NRC observers' findings related to the QA and programmatic areas of each AMR are provided for each AMR in Section 4.6 of this report.

4.5 Data Qualification

During the observation of the Waste Form PMR audit, the NRC observers met with the DOE and M&O to obtain information on the process being used to qualify data, software, and models supporting the site recommendation (SR) and the license application (LA). The status for the qualification of software and models is not addressed in this report. DOE has indicated that all software and models will be qualified at the time it submits the LA for the high-level waste repository at Yucca Mountain.

Background

In 1998 and 1999, the DOE identified several significant conditions adverse to quality and as a result, the quality of data and computer codes (software) supporting the SR and LA, qualified before June 1999, under DOE's QA Program, was identified as indeterminate and "suspect." The DOE determined that these data and software needed to be re-qualified and identified the status of these data, in a database, as "To Be Verified" (TBV).

In the fall of 1999, the DOE decided to categorize and prioritize the qualification data and software supporting the SR and the LA, based on their importance to waste isolation and importance to safety, using the broad criteria contained in the "Repository Safety Strategy (RSS)," Revision 3. The RSS contains the plan for preparing the post-closure safety case to support the SR and the LA. The RSS evaluated the natural and engineered barrier systems relative to their rōles in preventing or mitigating the release and migration of radionuclides to the public.

The RSS identifies seven principal factors, disruptive events, and 20 other factors that contribute to the performance of the proposed high-level waste repository at Yucca Mountain. The seven principal factors represent those repository performance features that provide the preponderance of waste isolation performance. The seven principal factors are: 1) seepage into drifts; 2) performance of the drip shield; 3) solubility limits of dissolved radionuclides; 4) retardation of radionuclide migration in the unsaturated zone; 5) retardation of radionuclide migration in the unsaturated zone; 6) retardation of radionuclide migration in the saturated zone; and 7) dilution of radionuclide concentrations during migration. Disruptive events include earthquakes and volcanism.

The DOE informed the NRC that it would be applying a graded approach to the qualification of data supporting the SR and the LA. The DOE plans to categorize data related to a disruptive event or one of the seven principal factors as high-risk significant, and data related to the other 20 factors as low-risk significant. High-risk significant data, identified as "suspect" data, will be subjected to re-qualification. Low-risk significant data, identified as "suspect" data, will not be subjected to re-qualification, unless during the re-qualification of similar high-risk significant data, problems are identified.

DTNs will be assigned to data once the data have been confirmed as inputs to analyses, calculations, software, and models required to support the SR and the LA. Because the entry of data into the DTN system continues to occur well into the analytical development process, the actual inventory of DTNs subject to qualification and verification is dynamic and will not be finalized until near the end of the AMR and PMR completion process.

Basis for Not Re-Qualifying "Suspect" Low-Risk Significant Data

The review provisions contained in AP-3.15Q, Revision I, ICN-0, were revised and now provide specific guidance for reviewing data that were identified as "suspect" data and for determining if these data are low- or high-risk significant. This procedural change was an attempt to incorporate a graded approach to data re-qualification activities. AP-3.15Q requires that previously qualified high-risk significant data related to the principal factors and disruptive events identified in the RSS Report be re-verified to remove their TBV status. AP-3.15Q presently requires no re-qualification for "suspect" low-risk significant data (previously qualified data not related to the RSS principal factors and disruptive events) and permits this low-risk significant data to be categorized as Qualified-Verified Level 2 data, with no re-qualification required.

During the audit, the NRC observers expressed a concern that it appears AP-3.15Q has eliminated the need to apply any QA controls for re-verifying the quality of these data. Therefore, if data are determined to be Quality-Verified Level 2, the TBV can be lifted without performing any re-verification activities.

The NRC observers discussed the risk-informed graded QA process with the DOE. It was noted that this process consists of several elements, such as risk categorization, grading the QA controls, corrective action, feedback, etc. Further, it was discussed that AP 3.15Q appears to have only addressed risk categorization (e.g., whether or not data are high- or low-risk significant) and not other elements of the graded QA process.

The NRC observers expressed a concern that the basis for eliminating and not grading the QA controls for low-risk significant re-qualification activities is not documented. Thus, it appears that AP-3.15Q has not applied reduced QA controls for the re-verification of these data, but is applying no QA controls. It was further discussed that categorizing data as low-risk significant should not be the basis for eliminating QA controls, but should be the basis for permitting reduced QA controls to be applied for re-verifying data categorized as low-risk. Reduced QA controls need to be identified and the basis for not performing any re-verification of Quality-Verified Level 2 data needs to be documented. Additionally, it was discussed that reduced QA controls could be the use of a sample plan or other graded verification activities. Depending on the results of these reduced QA controls, there may then be justification to eliminate the need to re-verify data that is categorized as low-risk significant/Quality-Verified Level 2.

The DOE and M&O agreed that the basis for not re-qualifying low-risk significant data was that: (a) it was low risk-significant; and b) except for very minor documentation problems, there had been no problems with the re-qualification of high-risk significant data qualified to date. Also, the DOE agreed there should be a feedback mechanism in place to identify the need for re-qualification of certain low-risk significant data should the re-qualification of similar high-risk significant data identify problems with these data.

The DOE and M&O agreed that the sample plan serving as the basis for its re-qualification of low-risk significant data needs to be formally documented in a procedure and needs to address feedback and corrective action (e.g., identify the process used to evaluate the need to re-qualify low-risk significant data). DOE informed the NRC observers that this sample plan would be incorporated into a procedure by the end of February 2000.

Status of Data Qualification Activities

During the observation, the DOE provided information on its progress of reaching its goal of having 50 percent of the data supporting the SRCR completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or DTNs out of a projected 1600 DTNs. During the audit, the NRC observers expressed a concern about the lack of data qualification activities for the AMRs reviewed during the audit and the four previous audits. This appears to be a condition requiring DOE's management attention.

4.6 Observation and Examination of Audit Programmatic and Technical Activities

The NRC staff observed the audit team (auditors and technical specialists) conducting detailed checks of the programmatic and technical adequacy of each AMR within the scope of the audit. The auditors and technical specialists used a combination of technical issue probing and procedural compliance checks and verifications to thoroughly consider both the technical adequacy of the AMRs and the effectiveness of implementation of the QA Program. The NRC staff's observations for each of the AMRs audited are discussed in the following sections.

4.6.1 AMR No. F0045 (ANL-EBS-MD-000048), "Initial Cladding Condition"

This report analyzes the cladding condition of the commercial spent nuclear fuel (SNF) as it is received at the Yucca Mountain (YM) repository. Because most commercial SNFs are encased in Zircaloy cladding, the analysis is developed to describe the degradation of Zircaloy from various sources. Primarily, Zircaloy-4 was analyzed since it represents all Zircaloy on a conservative basis in the cladding degradation. The analysis includes impacts from commercial nuclear power plant reactor operations such as incipient failures, degradation after reactor operation during wet or dry storage, and impacts from transportation. The potential degradation modes considered include creep, wall thinning from oxidation and crack development, delayed hydride cracking, and mechanical failure. The analysis defines the ranges and uncertainties of involved parameters. This analysis will serve as the initial boundary condition for the analysis of cladding degradation during the disposal period.

4.6.1.1 General Observations (Technical and Programmatic)

The checklist that the auditor prepared was extensive, thorough, and appropriate, indicating that both the auditor and technical specialist understood the AMR well. The AMR preparer answered most of the questions properly, and agreed to add several clarifications and editorial changes to the AMR text. After each section of the AMR had been reviewed by a DOE auditor and technical specialist, the NRC observer was provided an opportunity to asked additional questions and to comment on the AMR. The preparer agreed to modify the AMR and incorporate both the audit team and NRC observer's comments. The following paragraphs address the more significant recommendations made by the DOE audit team and the NRC observer.

4.6.1.2 Technical Observations

The DOE audit team provided the following recommendations:

a) Although the analysis was conducted using data from various literature sources, this data needs to be identified and submitted and justified as "accepted data." The technical specialist questioned whether some of these data should be submitted for review as "accepted" or as data to be qualified (e.g., the data on burn-up distribution needs to be submitted and qualified).

b) During the audit, the DOE technical specialist briefly reviewed five AMRs related to the initial cladding condition AMR, to determine the degree to which other cladding degradation AMRs and calculations were integrated and consistent in their use, with outputs from the initial cladding condition AMR. As a result of this review, the DOE technical specialist recommended that a thorough, in-depth, assessment be performed by all preparers of cladding degradation AMRs to ensure that their AMRs adequately and appropriately acknowledged and referenced the proper usage of assumptions, inputs, analyses, and results from the initial cladding condition AMR. The integration of the initial cladding condition AMR with related AMRs, such as the AMR on mechanical degradation, is recommended. The initial conditions developed in the initial cladding condition AMR need to be used in other AMRs. For example, the cladding thickness adjusted by the oxide formation needs to be used in the AMR on mechanical degradation where, currently, the oxide thickness is not taken into account in the input of the cladding thickness.

The NRC observer provided the following recommendations:

a) The localized corrosion, stress corrosion cracking (SCC), and hydride embrittlement (HE) caused by hydride reorientation need to be addressed, as identified in the NRC Issue Resolution Report (IRSR) on Container Life and Source Term (CLST). SCC and HE were identified in the audit checklist as review areas and, when questioned by the audit team, the originator responded that these would be covered in the related AMRs such as the "Features, Events, and Processes" AMR. The NRC observers recommended extending the coverage to localized corrosion in the related AMRs, and discussed that for these failure modes, this AMR needs to reference all the related AMRs. Further, it was discussed that where SCC and HE are discussed, they should consider and address the NRC IRSRs, especially the CLST IRSR, and the previous NRC/DOE interactions such as the Appendix 7 meeting on CLST in 1999. Further, it was discussed that unlike localized corrosion or SCC, the failure caused by HE may need to be fully analyzed in this AMR because it is likely to occur during storage and the transportation.

b) The effects of the weldment on the cladding performance need to be considered. For example, the fabrication-related failure during the reactor operation in Table 8 of the AMR needs to be extended to failures occurring during storage and transportation.

c) The creep failure criteria are not well-defined. The current criteria, an average strain at failure of 3.3 percent with a range of 0.4 percent to 11.7 percent, are not based on the

microstructural definition. For example, the NRC Review Plan for Dry Cast Storage adopts the diffusion controlled cavity growth (DCCG) criterion derived from cracking at grain boundaries. Although it is debatable whether the DCCG criterion needs to be adopted here, the failure criteria chosen here need to be sufficiently rationalized.

d) The Zircaloy-4 Pressurized Water Reactor cladding may not represent the Zircaloy-2 Boiling Water Reactor cladding on the conservative performance basis. This is of concern if the failure mode is extended from corrosion to hydride embrittlement.

The preparer agreed to address the following less significant topics: (a) providing a stronger technical basis and clear articulation of the framework associated with several assumptions and criteria used in the analysis; (b) test methods such as the use of irradiated or unirradiated samples at various temperatures need to be better-justified; (c) the primary sources of references will be quoted; (d) the chosen creep model needs to be better validated; (e) the terminology for the oxide thickness and the metal loss thickness should be clarified; (f) the experience and test results in storage will be updated; (g) the burn up effects on oxidation needs to be better stated; and (h) references on the DIRS form needs to be better-defined.

4.6.1.3 Programmatic Observations

There was no software requiring qualification for the initial cladding condition AMR; however, just before the audit, the AMR was updated as a result of a self-assessment. This update included a revision to identify the AMR's usage of the Excel spreadsheet application as a routine. The AMR was updated to include the appropriate information and test case to justify the software application as a routine.

There were no data qualification activities completed for the initial cladding condition AMR. Several data inputs existed. The preparer had not initiated any action to enter these data into the data tracking system.

4.6.2 Colloid AMRs - General Observations

This section contains the NRC staff observations of the DOE audit of the three colloid AMRs. Comments on specific colloid AMRs are addressed in Sections 4.6.3 through 4.6.5 of this report. The colloid abstraction AMR No. F0115 (ANL-WIS-MD-000012) provides direct input to the DOE total-system performance assessment (TSPA) in the form of a model abstraction describing colloid-associated radionuclide release from the waste form to the exterior of the waste package. The two additional colloid AMRs audited were AMR No. F0110 (ANL-EBS-MD-000020) and AMR No. F0105 (ANL-EBS-MD-000021). These AMRs provide direct data input to the abstraction AMR. During the audit, 2 days were devoted to the abstraction AMR, and 1 day for each of the two data AMRs.

4.6.2.1 General Technical Observations

The DOE audit team interviewed the AMR preparers and other AMR support personnel and performed a thorough review of the AMR and its supporting documentation. Although the assigned DOE technical specialist was not an expert in the field of colloid formation and transport, the technical specialist was well-qualified for conducting the audit and had a good

understanding and knowledge of technical context and aspects of the AMRs. His questions were appropriately focused on the transparency and traceability of the process leading to the colloid release abstraction. The technical specialist focused on both adherence to procedures and technical quality. The NRC technical specialist was afforded full participation, receiving ample time for follow-up questions and being allowed to raise new issues when appropriate within the scope of the audit. When warranted, the DOE technical specialist used issues raised by the NRC technical specialist in formulating his own recommendations. The NRC technical specialist's questions were adequately answered and no NRC audit observation inquires were needed. Although the DOE technical specialist controlled the agenda and was prepared to uncover inadequacies and recommend remedies, the sessions were nevertheless informal and collegial.

All three colloid AMRs were complete only through author-final status (Revision 00A) and were still in the checking stage. Therefore, it was not possible to assess fully the adequacy of the AMR process for producing reports of high quality and technical defensibility. Many of the issues raised by the technical specialists had previously been noted in the checking process, but it was apparent that the audit served as an in-process quality improvement exercise. In this sense, the audit did not completely fulfill its objectives.

The checker for two of the AMRs was present for the audit, providing much technical depth to the discussions. His presence was also useful in obtaining information on the ongoing checking process. In addition, it was indicated during the audit that the checker would likely head an effort to integrate colloid-related activities across PMRs and AMRs, assuring consistency in data and model treatments. Based on the checker's performance in the audit, it appears that this integration effort may serve as a model for other technical areas.

The AMRs reflected work of high technical quality. As noted by the DOE technical specialist, the abstraction AMR (see Section 4.6.3 of this report) was well-structured in showing the process leading from data input to abstraction output. However, there were general areas where improvement in the AMR preparation could be made. The three AMRs, collectively, could have been better integrated by making their inputs and outputs more explicit. A possible remedy, for example, would be to include in the conclusions section of the data AMRs lists of parameters, the parameter ranges, and plots that constitute the direct input to the abstraction AMR. In addition, the AMR preparation could be more explicitly directed toward effects on repository performance. As part of confidence building and model validation, the reports did contain data and references supporting their choices of data and models. However, these supporting technical bases did not always directly address whether the choices made could lead to potentially underestimating adverse effects on performance under repository conditions. Such a focus at the AMR level would better serve the DOE in making its safety case.

4.6.2.2 General Programmatic Observations

Technical and programmatic audit activities were conducted in accordance with the OQA Audit Plan for Audit M&O-ARP-00-005. The auditors and technical specialists reviewed documents identified in the audit plan and used checklists as a basis for inquiries. In addition, related documentation supporting report development and conclusions was reviewed to verify data source and status of qualification. Personnel directly responsible for document products or appropriate representatives with sufficient levels of knowledge were interviewed, including

personnel from the Los Alamos National Laboratory (LANL), Argonne National Laboratory (ANL), and Lawrence Livermore National Laboratory. The checklists used were effective and additional inquiries were made beyond specific checklist items, when appropriate.

4.6.3 AMR No. F0115 (ANL-WIS-MD-000012), "Waste-Form Colloid-Associated Concentration Limits: Abstraction and Summary"

The abstraction AMR was the main focus of the colloid sessions of the audit, because it represents the handoff of the model abstraction for colloid release from the waste form to TSPA. The AMR uses literature and Yucca Mountain Project data to support its construction of an algorithm for calculating colloid-associated radionuclide concentrations in solutions leaving the waste package (no credit is taken for colloid retardation within the waste package). Direct inputs for conceptual models and parameters were obtained from the two supporting AMRs that were reviewed during this audit. Also, a small number of literature sources that will be subjected to the DOE data acceptance procedure were used as inputs. The abstraction uses output from in-package geochemical models and uses pH, ionic strength, and dissolved radionuclide concentration to calculate colloid concentrations, irreversibly colloid-bound radionuclide concentrations, and reversible colloid binding of radionuclides. The results are combined to provide a total colloid-associated source term for a given radionuclide.

4.6.3.1 Technical

The preliminary status of this AMR was partly compensated for by the presence, at the audit, of its checker. The checker suggested revisions, to be incorporated into Revision 00B of the AMR, that were substantial, and addressed many of the technical concerns expressed by both the audit team and NRC technical specialists. The substantive revisions were, for the most part, in the areas of strengthening technical bases and clarifying the abstraction through the use of flow charts and logic statements. The checking process led to improvement in report quality.

A useful feature of this AMR was a pair of tables describing how the report addresses NRC IRSRs and the DOE's performance assessment (PA) peer review panel recommendations. This table should serve as a model for other AMRs, because it clearly facilitates using the information in the report to further issue resolution.

This AMR needed improvement in providing justification for assumptions and choices of data and models. Model validation exercises were scattered throughout the document and, at the suggestion of the DOE technical specialist, will be consolidated in the report. However, the technical bases were typically not explicit enough with respect to repository performance. The checker helped to correct many of these shortcomings, but direct relevance to the proposed repository in AMR preparation should be better emphasized early in the process. For example, the abstraction adopted a maximum concentration of plutonium irreversibly attached to colloids of 6×10^{-8} mol/L, based on results of 15 ANL experiments on static HLW glass degradation (reported in ANL-EBS-MD-000020 Rev 00A). The literature on this topic is admittedly sparse, but the AMR did not make a strong case that this value is likely to bound plutonium concentrations under particular repository conditions that may not be reflected in experiments using EJ-13 or deionized water at 90°C.

The abstraction was stated to apply only to plutonium and americium. However, no technical basis was provided for the choice of these radioelements and the exclusion of others. The author planned to add other elements, but such questions of scope should be addressed early in the process.

A preliminary list provided by the DOE technical specialist contained seven recommendations for improving the abstraction AMR. No formal deficiencies were issued. Most recommendations focused on strengthening or clarifying technical bases and addressing issues such as model validation and uncertainty. A notable recommendation was that model validation in the AMR be augmented with results of test runs of the abstraction within the Total System Performance Assessment (TSPA) code. A programmer has begun coding this abstraction into TSPA, and provided the audit team with a demonstration of the GoldSim software being used for TSPA. The audit team, observers, and the individuals being audited all agreed that code testing should, when possible, be a component of model validation for inclusion in the abstraction AMR - and not only within the TSPA effort.

4.6.3.2 Programmatic

The DIRS forms had been completed for this AMR. Twenty-five data packages had been identified as "TBV." After discussion on the use of "reference," "corroborative," and "accepted" data, the author stated the "B" revision of the AMR DIRS would only identify about four data sets as "TBV." This indicated that recommendations from previous OQA audits and the M&O Lessons Learned program have not been effective in communicating these issues with the AMR authors. The governing procedure, AP-3.15Q, clarified some of the above issues. However, discussions with the procedure author indicated the training plan is currently under development and has not been presented to any personnel.

A discussion occurred on whether data abstraction could be classified as a model. The governing procedure AP-3.10Q was not clear. The procedure author stated that the procedure revision was currently undergoing the management review process. During the discussion, notes were taken for clarification in the next procedure revision.

No software programs requiring qualification were noted with this AMR.

The planning documents and information contained in the Technical Data Tracking System (TDMS) were found to be acceptable.

4.6.4 AMR No. F0105 (ANL-EBS-MD-000021), "Colloid Stability and Attachment/Detachment Properties"

This AMR describes literature data and Yucca Mountain Project laboratory studies on colloid stability and colloid sorption of radionuclides. This AMR provides direct input to the abstraction AMR (ANL-WIS-MD-000012) in the form of a range of sorption coefficients, or K_ds, to be used in modeling reversible attachment of plutonium to colloids. The K_ds were based on batch colloid sorption experiments at LANL, which were obtained under the current DOE QA program and therefore are expected to be qualified. This report was at an even more preliminary stage than the abstraction AMR, having received only a preliminary read-through by the checker. As a result, the report is expected to be substantially revised.

4.6.4.1 Technical

The DOE audit team identified the need for several improvements for this AMR, including addressing the issues of clarity of outputs and confidence building in the context of repository performance previously discussed. For example, the direct output to the abstraction AMR was difficult to discern because it was not emphasized and restated at the end of the report. In addition, no technical basis was provided for the use of the mass-based coefficient K_d rather than the surface-area based coefficient K_A.

Two additional general areas in which the AMR could be improved are in the inappropriate focus on future work and the level of experimental detail. Because of emphasis, in the conclusions section on the paucity of relevant colloid sorption data, the draft report read more like a proposal than a data input report. In addition, the report omitted important experimental details such as pH variation during the experiments. This information was needed to support the applicability of the results. It appeared that the checker was addressing both of these issues in his comments.

A preliminary list provided by the DOE technical specialist contained five recommendations for improving the LANL AMR. No formal deficiencies were issued. These recommendations were appropriately focused on clarity, improving the technical bases supporting the results of analysis, and the applicability of these results to the proposed repository.

4.6.4.2 Programmatic

Planning documents for this AMR were found to be in accordance with applicable procedures.

The LANL scientific notebook containing the results of analyses and testing was reviewed during the audit and its author interviewed. This review indicated that the loose-leaf binder was in compliance with Procedure No. AP-S111.1Q. The notebook entries and required reviews were properly documented with no discrepancies noted. A recommendation was made to transmit this document to the DOE Records Center and have it entered into the TDMS before the issuance of Rev 00 of the AMR. The DIRS document indicated three sets of data requiring qualification and were identified by TBVs 0473, 0869, and 3348. No software packages required qualification for this AMR.

4.6.5 AMR No. F00110 (ANL-EBS-MD-000020), "Colloid-Associated Radionuclide Concentration Limits"

This AMR contains literature and previous ANL data from static and drip corrosion tests on HLW glass and SNF supporting a model of irreversible plutonium colloid attachment used in the colloid source term abstraction AMR. The direct inputs to the adopted abstraction were all based on ANL work and are: (a) a relationship between colloidal plutonium concentration and ionic strength, based on static HLW glass corrosion tests; (b) a relationship between ionic strength and colloid stability; and (c) a direct relationship between colloidal plutonium concentration and colloid concentration. The adopted abstraction uses data only from the HLW glass tests. The SNF results were included in the development of a model in an AMR that was used in the abstraction AMR as an alternative model. The use in the abstraction only of HLW

glass results appears to be conservative in that the ANL AMR concluded that colloid release was lower in SNF tests.

4.6.5.1 Technical

As was the case for the other AMRs, this report was of high technical quality and no significant differences over technical approaches were discussed. However, as previously discussed, adequately addressing the issues of clarity of outputs and confidence building was an area needing improvement. For example, the AMR needed to contain stronger justification that: a) the test samples were sufficiently representative of the range of waste forms expected in the proposed repository; b) deviation of repository physical and chemical conditions from those in the laboratory have been properly considered; and c) neglecting the effects of water chemical parameters other than pH and ionic strength in characterizing colloid behavior is appropriate.

A preliminary list provided by the DOE technical specialist contained four recommendations for improving the AMR. No formal deficiencies were issued. These recommendations were appropriately focused on clarity, uncertainty, and improving technical bases supporting the results and their applicability to the proposed repository.

4.6.5.2 Programmatic

The DIRS document contained 30 entries for data identified as "Qualified Verification Level 2," in accordance with procedure AP3.15Q. No software programs requiring qualification were noted for this AMR.

The work performed at ANL was governed by a subcontract from the M&O. The laboratory is listed on the Approved Vendors List and requires the DOE's annual evaluation and triennial audit of its quality system.

Various ANL scientific notebook pages identified on the DIRS form were pulled from the TDMS. No discrepancies were noted; however, a recommendation was made to have the complete scientific notebooks submitted to the Records Center.

4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff generally agrees that OQA Audit M&O-ARP-00-005 was effective in recommending improvements in the AMR process and with the audit team conclusions, findings, and recommendations. The audit was conducted in a professional manner, using audit team members who were independent of the activities they audited. The DOE audit team members appeared to be knowledgeable in the QA and technical disciplines within the scope of the audit. Their qualifications were found to be acceptable for their respective disciplines. Although the audit scope included data qualification, the audit team was unable to assess the data qualification process and activities, because no data-qualification activities had been performed for the data supporting the AMRs reviewed.

During the observation, the DOE provided information on the progress in reaching its goal of having 50 percent of the data supporting the SRCR completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or DTNs out of a projected 1600 DTNs. The

DOE explained that the total number of DTNs was still evolving because several AMRs preparers had not entered the data supporting the AMRs into the DTN tracking system. During the audit, the NRC staff expressed a concern about the lack of data qualification activities for the AMRs reviewed during the audit and the four previous audits. The NRC staff considers the lack of data qualification activities during this audit and the four previous PMR audits to be a condition requiring OQA management attention. The NRC staff suggests that OQA management evaluate the need to conduct audits specifically to evaluate the qualification of data.

Because the AMRs reviewed were in draft and in the process of being completed, the DOE audit served more as a review than as an assessment. No deficiencies were written. Technical discussions held during the audit were informal and detailed and at times resembled a technical exchange. The DOE technical specialist appropriately focused the discussions on transparency and traceability in the processes of data acquisition, data interpretation, model development, and validation. The colloid abstraction AMR appears to be a good example for illustrating an acceptable model development and model validation. It is recommended that M&O consider using this example as part of the training given to AMR preparers.

The preparers of AMRs need to provide more considerations to the regulatory process and issues of repository performance. In addition to the AMR being a sound technical document, it should also provide more explicit technical bases so that choices of data and models will not lead to underestimates of potentially adverse effects on repository performance.

During the audit the NRC observers questioned DOE's basis for not performing re-qualification of low-risk significant data. The DOE informed the NRC observers that the sample plan, serving as the basis for not performing re-qualification of low-risk significant data, would be documented in a procedure by the end of February 2000, and would provide for feedback and corrective action, should problems be identified in re-qualifying similar high-risk significant data.

The NRC observers concluded that: (a) the AMR developers, within the scope of this audit, produced technically adequate AMRs; however, both the NRC observers and OQA audit team members provided several comments on the technical content of the AMRs; (b) the DIRS, which is used to track DTNs, has improved; and (c) the implementation of changes to procedures controlling the AMR process and the communicating of lessons learned from the audits to the preparers of the AMRs could be improved by providing additional training or formal instruction.

M&O focus has been placed on AMR packages undergoing OQA review, which covers only a small percentage of the total number of AMRs and PMRs being developed. This calls into question the adequacy and condition of the remaining AMR/PMR packages not undergoing the same scrutiny.

4.7.1 Audit Observer Inquiries (AOI)

No NRC AOIs were generated during this audit.

4.7.2 Closure of Previous NRC AOIs

No AOIs were closed during the conduct of this observation.

4.7.3 Open NRC AOIs

The following NRC AOIs remain open:

a) AOI No. OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999: AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999: Documented resolution of individual comments is not required for checks of analysis and models (AP-3.10Q) and is optional for reviews of technical products (AP-2.14Q). A lack of documented resolution is inconsistent with the QARD Section 2.2.10 (f), which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.